General

Guideline Title

Otitis media.

Bibliographic Source(s)

University of Michigan Health System. Otitis media. Ann Arbor (MI): University of Michigan Health System; 2013 Apr. 12 p. [15 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System (UMHS). Otitis media. Ann Arbor (MI): University of Michigan Health System (UMHS); 2007 July. 12 p. [13 references]

The University of Michigan Health System released a minor revision in March 2014 to include information from the American Academy of Pediatrics that was released after the April 2013 publication of this guideline.

Recommendations

Major Recommendations

Note from the University of Michigan Health System (UMHS) and the National Guideline Clearinghouse (NGC): The following guidance was current as of April 2013. Because UMHS occasionally releases minor revisions to its guidance based on new information, users may wish to consult the original guideline document for the most current version.

Note from NGC: The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, possible side effects, and cost of medications, as well as considerations for special populations and special situations.

The strength of recommendation (I-III) and levels of evidence (A-D) are defined at the end of the "Major Recommendations" field.

Diagnosis

- Distinguish between acute otitis media (AOM) and otitis media with effusion (OME). Symptoms of pain or fever, together with an inflammatory middle ear effusion, are required to make a diagnosis of AOM *[I, D]*.
- The presence of middle ear effusion should be determined by the combined use of otoscopy, pneumatic otoscopy, and tympanometry when necessary *[I, D]*.

Therapy of AOM

- Recommend adequate analgesia for all children with AOM *[I, D]*.

- Consider deferring antibiotic therapy for lower risk children with AOM *[II, A]*.
- When antibiotic therapy is deferred, facilitate patient access to antibiotics if symptoms worsen (e.g., a "back-up" prescription given at visit or a convenient system for subsequent call-in) *[I, C]*.
    - Amoxicillin is the first choice of antibiotic therapy for all cases of AOM.
      Children:
        - Dosing: <4 years, 80 mg/kg/day divided twice a day (BID); ≥4 years, 40-60 mg/kg/day *[I, C]*.
        - Duration 5-10 days: 5 days is usually sufficient at lower cost and fewer side effects, although 10 days reduces clinical failure *[A]*. Consider 10-day course for children with significant early upper respiratory infection (URI) symptoms and <2 years old, with possible sinusitis, and with possible strep throat *[II, D]*.

      Adults: either 875 mg BID x 10 days or 500 mg 2 tabs BID x 10 days *[I, C]*.

    In the event of allergy to amoxicillin, azithromycin (Zithromax) dosed at 30 mg/kg for one dose is the appropriate first line therapy.

- Treat AOM that is clinically unresponsive to amoxicillin after 72 hours of therapy with amoxicillin/clavulanate (Augmentin ES; amoxicillin component 80 mg/kg/day divided BID) for 10 days or with azithromycin (Zithromax) 20 mg/kg daily for 3 days *[II, C]*.
- Patients with significant, persistent symptoms on high-dose amoxicillin/clavulanate (Augmentin ES) or azithromycin (Zithromax) may respond to intramuscular (IM) ceftriaxone (Rocephin; 1-3 doses) *[II, C]*. The decision to use ceftriaxone (Rocephin) should take into account the negative impact it will have on local antibiotic resistance patterns.

Therapy of OME

- Children with middle ear effusions should be examined at 3 month intervals for clearance of the effusion *[I, D]*.
- Children with evidence of mucoid effusions or anatomic damage to the middle ear should be referred to otolaryngology if effusion or abnormal physical findings persist for 3 months *[I, D]*.
- Children with apparent serous effusions should be referred to otolaryngology if effusion persists for 6 months and there is evidence of hearing loss or language delay *[I, D]*.
- Children with an asymptomatic middle ear effusion (no apparent developmental or behavioral problems) can be followed without referral *[I, B]*.
- Parents of all children with OME should be informed about approaches to maximize language development in a child with a possible hearing loss *[I, C]*.
- Decongestants and other nasal steroids have been shown not to decrease middle ear effusions *[IIIA]*.

Definitions:

Levels of Evidence Supporting a Diagnostic Method or an Intervention

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Otitis media, including:

Acute otitis media (AOM)
Otitis media with effusion (OME)

Guideline Category

Diagnosis

Management

Treatment

Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Otolaryngology

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

- To limit acute symptoms and suppurative complications caused by acute otitis media (AOM)
- To maximize language development and minimize long term damage to middle ear structure associated with otitis media with effusion (OME)
- To limit complications of antibiotic therapy including the development of antibiotic-resistant bacteria

Target Population

Pediatric patients (>2 months old) and adults

Interventions and Practices Considered

Diagnosis

1. Distinguishing between acute otitis media (AOM) and otitis media with effusion (OME)
2. Presence of middle ear effusion (MEE)
    - Otoscopy
    - Pneumatic otoscopy

    - Tympanometry
3. Evaluation for symptoms (otalgia, irritability, fever) and signs of inflammation

Management of AOM

1. Analgesics (ibuprofen, acetaminophen, topical analgesics)
2. Observation versus initiating antibiotic therapy (deferred therapy with access to antibiotics if condition worsens)
3. Antibiotics
    - First-line: high dose amoxicillin
    - High dose azithromycin for patients allergic to amoxicillin
    - High dose amoxicillin/clavulanate or azithromycin for persistent symptoms despite initial amoxicillin
    - Ceftriaxone for episodes of clinical failure or suspected serious bacterial infection
4. Management of recurrent AOM, including preventive measures (immunizations, reduction in exposure to passive smoke, treatment of gastroesophageal reflux, consideration of placement of tympanostomy tubes)

Management of OME

1. Clinical reevaluation at 3 month intervals
2. Referral to otolaryngology for persistent abnormal findings or complications (hearing loss or language delay)
3. Parental education regarding approaches to maximizing language development
4. Decongestants and nasal steroids (not recommended)

Management of Special Circumstances

1. Management of special populations (infants 0-8 weeks old, children with chronic illnesses, otitis media in adults)
2. Tympanostomy tube management
3. Cerumen removal
4. Otorrhea and acute otitis externa (AOE)

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Degree of symptomatic improvement
- Bacteriologic and clinical response rates to treatment
- Rates of antibiotic resistance
- Complication rates (e.g., hearing loss, speech language delays)
- Medication and treatment side effects

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The guideline team had access to the literature searches performed for the initial version of this guideline (1997) and its updates (2002, 2006). For this update the literature search began with a review updated Agency for Healthcare Research and Quality (AHRQ) Evidence Report on Management of Acute Otitis Media, which included a systematic review of literature through July 2010 (see annotated references in the original guideline document). To supplement these searches with more recent findings, the team then conducted a prospective search of literature published on Medline from 7/1/10 to 9/30/12 (unless otherwise noted) using the major keywords of: human, English language, guidelines, controlled trials, and cohort studies. Eleven specific searches were performed using the following terms. Detailed search terms and strategy available upon request.

1. Otitis media with effusion or serous effusion: audiogram or otoacoustic emissions, diagnosis, treatment (since 6/1/06)

2. Recurrent otitis media, recurrent acute OM, or chronic or persistent OM: diagnosis, treatment
3. Acute otitis media since (not recurrent, persistent, or chronic [addressed in #2]): etiology and natural history, diagnosis (signs and symptoms, hearing loss, delayed language development, otoscopy, pneumatic otoscopy, tympanometry, tympanocentesis, other diagnosis). treatment (antibiotic therapy [amoxicillin, cephalosporins, other antibiotics], adjunctive therapy (corticosteroid, antihistamines, decongestants, other), myringotomy or tympanostomy tubes, laser tympanostomy or laser myringotomy, complementary/alternative treatment (since 1/1/2001), other treatment
4. Otitis media: infants 0–4 weeks (since 1/1/2001), diagnosis, treatment
5. Otitis media: adults (since 1/1/2001), diagnosis, treatment
6. Otitis media and mastoiditis
7. Otitis media and screening for speech delay
8. Otitis media not in #1–#7: diagnosis, treatment
9. Cerumen impaction: treatment (since 6/1/06)
10. Otorrhea: treatment
11. Probiotic bacteria after antibiotics (since 6/1/06)

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence Supporting a Diagnostic Method or an Intervention

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Expert consensus was used to formulate recommendations based on the available evidence (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Drafts of this guideline were reviewed in clinical conferences and by distribution for comment within departments and divisions of the University of Michigan Medical School to which the content is most relevant: Family Medicine, General Internal Medicine, General Pediatrics, Pediatric Infectious Disease, and Pediatric Otolaryngology. The guideline was approved by the University of Michigan C. M. Mott Children Hospital's Pediatric Medical Surgical Joint Practice Committee and Executive Committee. The Executive Committee for Clinical Affairs of the University of Michigan Hospitals and Health Centers endorsed the final version.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for the most significant recommendations (see the "Major Recommendations" field).

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size. Expert consensus was used to formulate recommendations based on the available evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and effective treatment and management of otitis media

Potential Harms

- Clinicians overestimate the extent to which clinical failure is due to antibiotic resistance, and overestimate the likelihood that second line medications will cover resistant organisms.

- The use of beta-lactamase resistant antibiotics may promote colonization with resistant organisms.
- Diarrhea and candidal infections are among the most common complications of antibiotic therapy. Therefore parents should be warned about this in advance. It is also appropriate to provide recommendations about diaper care and the application of clotrimazole (Lotrimin) cream in the event of diaper rash. Giving yogurt with active cultures might also be helpful.
- Antibiotic administration in general, as well as for the management of acute otitis media (AOM), is frequently associated with the onset of diarrhea (occurring in up to 40% of patients). Although the diarrhea is usually self-limited, it can become more worrisome when associated with *Clostridium difficile*.
- Excessive use of azithromycin is associated with increasing rates of erythromycin resistance, particularly involving group A beta-hemolytic streptococci, and therefore its routine use should be discouraged. Cefuroxime (Ceftin) can also be used, although it is clinically inferior to amoxicillin. Third-generation cephalosporins, such as cefdinir (Omnicef), are not more effective and carry with them an excessive risk of selection of resistant bacteria.
- Although some children will likely benefit from intramuscular ceftriaxone, the decision to prescribe this agent should not be made lightly, the overuse of ceftriaxone is likely to significantly increase high level penicillin resistance in this population.
- Placement of ventilation tubes is also associated with an increased risk of long-term tympanic membrane abnormalities and reduced hearing compared to medical therapy.

Qualifying Statements

Qualifying Statements

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

University of Michigan Health System. Otitis media. Ann Arbor (MI): University of Michigan Health System; 2013 Apr. 12 p. [15 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1997 Nov (revised 2013 Apr)

Guideline Developer(s)

University of Michigan Health System - Academic Institution

Source(s) of Funding

University of Michigan Health System (UMHS)

Guideline Committee

Otitis Media Guideline Team

Composition of Group That Authored the Guideline

Team Leader: Heather L. Burrows, MD, PhD, General Pediatrics

Team Members: R. Alexander Blackwood, MD, PhD, Pediatric Infectious Disease; James M. Cooke, MD, Family Medicine; R. Van Harrison, PhD, Medical Education; Kathryn M. Harmes, MD, Family Medicine; Peter P Passamani, MD, Pediatric Otolaryngology

Consultant: Kristin C Klein, PharmD, UMH Pharmacy Services

Guidelines Oversight Team: Grant Greenberg, MD, MA, MHSA; R Van Harrison, PhD

Financial Disclosures/Conflicts of Interest

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member	Company	Relationship
R. Alexander Blackwood, MD, PhD	none	
Heather L Burrows, MD PhD	none	
James M. Cooke, MD	none	
Kathryn M. Harmes, MD	none	
Van Harrison, PhD	none	
Peter P Passamani, MD	none	
Kristin C Klein, PharmD	none	

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System (UMHS). Otitis media. Ann Arbor (MI): University of Michigan Health System (UMHS); 2007 July. 12 p. [13 references]

The University of Michigan Health System released a minor revision in March 2014 to include information from the American Academy of Pediatrics that was released after the April 2013 publication of this guideline.

Guideline Availability

Electronic copies: Available from the University of Michigan Health System Web site .

Availability of Companion Documents

The following are available:

- Otitis Media. What's new - cover memo. Ann Arbor (MI): University of Michigan Health System; 2013 Apr. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System (UMHS) Web site .
- Continuing Medical Education (CME) information is available from the UMHS Web site .

Patient Resources

The following are available:

- Ear infection (acute otitis media). University of Michigan Health System; 2013 May. 4 p. Electronic copies: Available from the University of Michigan Health System (UMHS) Web site .
- Otitis media: fluid in the middle ear. Diagram. 2011. 1 p. Electronic copies: Available from the UMHS Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI on January 7, 2003. The information was verified by the guideline developer on February 4, 2003. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-

inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This NGC summary updated by ECRI Institute on January 22, 2008. The updated information was verified by the guideline developer on February 11, 2008. This summary was updated by ECRI Institute on May 5, 2009, following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This summary was updated by ECRI Institute on August 12, 2013. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs).

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.